PATENT

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Anita Johnson

Applicant	:	Claudio P. Plaza	Confirmation No. 7287
Application No.	:	10/820,480	
Filed	:	April 2, 2004	
Title	:	IRRIGATED CATHETER HAVING A POROUS TIP ELECTRODE	
Grp./Div.	:	3739	
Examiner	:	Michael F. Peffley	
Docket No.	:	51991/W112	

APPELLANT'S BRIEF

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Post Office Box 7068
Pasadena, CA 91109-7068
June 15, 2010

Commissioner:

1. REAL PARTY IN INTEREST

The real party in interest is Assignee, Biosense Webster, Inc.

2. RELATED APPEALS AND INTERFERENCES

There are no other appeals or interferences that will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

3. STATUS OF CLAIMS

Claims 1-30 are pending in the application, and all of pending claims 1-30 have been rejected. The rejection of each of claims 1-30 is appealed.

4. STATUS OF AMENDMENTS

This appeal is taken from an Office Action dated January 15, 2010, which responds to an Amendment filed on January 4, 2010.

5. SUMMARY OF CLAIMED SUBJECT MATTER

Claims 1-30 have been rejected and are appealed. Of these claims, claims 1, 15, 29 and 30 are independent. Claim 1 is directed to an irrigated electrode catheter for ablating tissue, the catheter comprising a catheter body having proximal and distal ends and a lumen extending therethrough; a tip section having proximal and distal ends, the proximal end of the tip section being fixedly attached to the distal end of the catheter body; a porous tip electrode fixedly attached to the distal end of the tip section, the tip electrode comprising a non-conductive porous material and a conductive porous coating adapted to cover the non-conductive porous material, wherein the conductive porous coating has a thickness of about 0.2μm to about 2μm; and an irrigation tube extending through the catheter body and into the porous tip electrode of the tip section, whereby fluid passing through the irrigation tube can pass through the non-conductive porous material and the conductive porous coating to reach surrounding tissue. *Specification, page 4, line 12 through page 5, line 19; page 6, lines 26-32; page 8, lines 1-19; page 9, lines 8-29; page 11, line 18 through page 12, line 2; page 13, line 17 through page 14, line 31.* The irrigated electrode catheter can further comprise an electrode lead wire in electrical communication with the conductive porous coating. *Claim 2; specification, page 12, line 18 through page 13, line 6.* The non-conductive porous material may be made from material selected from the group consisting of polyethylene, Teflon and ceramic. *Claim 3; specification, page 9, lines 8-13.* For example, the non-conductive porous material may comprise polyethylene. *Claim 4; specification, page 9, lines 8-29.* The conductive porous coating may be made from a material selected from the group consisting of platinum and gold. *Claim 5; specification, page 11, lines 23-24.* The conductive porous coating may comprise an alloy of platinum and iridium. *Claim 6; specification, page 11, lines 24-28.* The alloy of platinum and iridium may comprise 90% platinum and 10% iridium. *Claim 7; specification, page 11, lines 24-28.* Fluid may pass through channels between particles of the non-conductive porous material. *Claim 8; specification, page 9, lines 24-29; page 14, lines 6-10.* The fluid may pass through channels of a webbing of the conductive porous coating. *Claim 9; specification, page 11, lines 33 through page 12, line 2; figures 8 and 10.* The irrigated electrode catheter may further comprise a temperature sensing means mounted within the tip electrode. *Claim 10;*

specification, page 14, line 32 through page 15, line 25. The irrigated electrode catheter may further comprise an electromagnetic sensor mounted in the tip section. *Claim 11; specification, page 18, line 4 through page 19, line 7.* The non-conductive porous material may comprise sintered polymer particles. *Claim 12; specification, page 9, line 8 through page 10, line 30.* The non-conductive porous material may comprise sintered ceramic particles. *Claim 13; specification, page 9, line 8 through page 10, line 30.* The polymer particles may comprise particles of polyethylene or Teflon. *Claim 14; specification, page 9, line 9 through page 10, line 30.*

Claim 15 is directed to an irrigated electrode catheter for ablating tissue, the catheter comprising a catheter body having an outer wall, proximal and distal ends, and a lumen extending therethrough; a tip section comprising a segment of flexible tubing having proximal and distal ends and at least one lumen therethrough, the proximal end of the tip section being fixedly attached to the distal end of the catheter body; a porous tip electrode fixedly attached to the distal end of the tubing of the tip section, the tip electrode having an outer surface and comprising a non-conductive porous material through which fluid can pass and a thin metal coating adapted to cover the non-conductive porous material, wherein the thin metal coating has a thickness of about 0.2μm to about 2μm; and an irrigation tube having proximal and distal ends extending through the central lumen in the catheter body, wherein the distal end of the irrigation tube is in fluid communication with the proximal end of the passage in the tip electrode, whereby fluid can pass through the irrigation tube, into the passage in the tip electrode and through the porous material of the tip electrode to the outer surface of the tip electrode. *Specification, page 4, line 12 through page 5, line 19; page 6, lines 26-32; page 8, lines 1-19; page 9, lines 8-29; page 11, line 18 through page 12, line 2; page 13, line 17 through page 14, lines 6-10 and 31.* The irrigated electrode catheter may further comprise an electrode lead wire in electrical communication with the thin metal coating. *Claim 16; specification, page 12, line 18 through page 13, line 6.* The non-conductive porous material may be made from material selected from the group consisting of polyethylene, Teflon and ceramic. *Claim 17; specification, page 9, lines 8-13.* For example, the non-conductive porous material may comprise polyethylene. *Claim 18; specification, page 9, lines 8-29.* The thin metal coating may be made from a material selected

from the group consisting of platinum and gold. *Claim 19; specification, page 11, lines 23-24.* The thin metal coating may comprise an alloy of platinum and iridium. *Claim 20; specification, page 11, lines 24-28.* The alloy of platinum and iridium may comprise 90% platinum and 10% iridium. *Claim 21; specification, page 11, lines 24-28.* Fluid may pass through channels between particles of the non-conductive porous material. *Claim 22; specification, page 9, lines 24-29; page 14, lines 6-10.* The fluid may pass through channels of a webbing of the thin metal coating. *Claim 23; specification, page 11, lines 33 through page 12, line 2; figures 8 and 10.* The irrigated electrode catheter may further comprise a temperature sensing means mounted within the tip electrode. *Claim 24; specification, page 14, line 32 through page 15, line 25.* The irrigated electrode catheter may further comprise an electromagnetic sensor mounted in the tip section. *Claim 25; specification, page 18, line 4 through page 19, line 7.* The non-conductive porous material may comprise sintered polymer particles. *Claim 26; specification, page 9, line 8 through page 10, line 30.* The non-conductive porous material may comprise sintered ceramic particles. *Claim 27; specification, page 9, line 8 through page 10, line 30.* The polymer particles may comprise particles of polyethylene or Teflon. *Claim 28; specification, page 9, line 9 through page 10, line 30.*

Claim 29 is directed to an irrigated electrode catheter for ablating tissue, the catheter comprising a catheter body; a tip section attached to the catheter body; a porous tip electrode fixedly attached to the tip section, the tip electrode comprising a non-conductive porous material and a conductive porous coating generally encapsulating the non-conductive porous material, wherein the conductive porous coating has a thickness of about 0.2μm to about 2μm; and an irrigation tube extending through the catheter body and into the porous tip electrode of the tip section, whereby fluid passing through the irrigation tube can pass through the non-conductive porous material and the conductive porous coating to reach surrounding tissue. *Specification, page 4, line 12 through page 5, line 19; page 6, lines 26-32; page 8, lines 1-19; page 9, lines 8-29; page 11, line 18 through page 12, line 2; page 13, line 17 through page 14, lines 6-10 and 31.*

Claim 30 is directed to an irrigated electrode catheter for ablating tissue, the catheter comprising a catheter body; a tip section attached to the catheter body; a porous tip electrode

fixedly attached to the tip section, the tip electrode comprising an inner non-conductive porous material and an outer conductive porous material, wherein the outer conductive porous material has a thickness of about 0.2μm to about 2μm; and an irrigation tube extending through the catheter body and into the porous tip electrode of the tip section, whereby fluid passing through the irrigation tube can pass through the non-conductive porous material and the conductive porous material to reach surrounding tissue. *Specification, page 4, line 12 through page 5, line 19; page 6, lines 26-32; page 8, lines 1-19; page 9, lines 8-29; page 11, line 18 through page 12, line 2; page 13, line 17 through page 14, lines 6-10 and 31.*

6. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Whether the Examiner erred in rejecting claims 1-30 under 35 U.S.C. §103(a) as obvious over Moaddeb, et al. (U.S. Patent No. 6,405,078)("Moaddeb") in view of Skalsky, et al. (U.S. Patent No. 4,844,099)("Skalsky") and Truckai, et al. (U.S. Patent No. 6,458,127)("Truckai").

7. ARGUMENT

Applicant submits that the Examiner has erred in continuing to reject claims 1-30 as allegedly obvious over Moaddeb, Skalsky and Truckai.

I. Rejection of claims 1-30 under 35 U.S.C. §103(a) as obvious over Moaddeb, Skalsky and Truckai

In the Office action dated January 10, 2010, the Examiner continues to rely on the combination of Moaddeb and Skalsky to arrive at the irrigated electrode catheter recited in the present claims. In particular, the Examiner relies on arguments made in previous Office actions in which the Examiner argues that "[i]t is improper for [A]pplicant to assume that the [Skalsky] electrode must be used in the same manner (i.e. to attach to tissue) when combined with the [Moaddeb] reference," and that "[t]he skilled artisan would not be required to use [the Skalsky] construction in the exact same manner and would realize that any porous electrode may be fabricated in [the Skalsky] manner and continue to be used for its intended purpose." June 10, 2009 Final Rejection, page 4. Applicant respectfully traverses.

As noted in MPEP §2143.02, obviousness requires a reasonable expectation of success, which can be shown if "all the claimed elements were known in the prior art *and* one skilled in the art could have combined the elements as claimed by known methods *with no change in their*

respective functions, and the combination would have yielded nothing more than predictable results to one of ordinary skill in the art." Here, the combination of Moaddeb and Skalsky would result in a significant *change in the respective functions* of the claimed elements. In particular, as noted in Applicant's previous responses, Skalsky discloses a pacing lead that is designed to remain in the heart. In order to accomplish this, the Skalsky lead is designed to facilitate attachment of the lead to tissue by promoting tissue ingrowth. See column 2, line 54 to column 3, line 8. Given this disclosure in Skalsky, those of ordinary skill in the art would have predicted that the Skalsky structure would promote tissue ingrowth and affix to tissue. As the catheter disclosed in Moaddeb is designed for temporary use during a relatively short procedure, a structure such as that described in Skalsky that promotes tissue ingrowth and affixes to tissue would significantly alter the function of the Moaddeb device.

Moreover, as Skalsky is directed to a pacing lead that attaches to tissue through tissue ingrowth, those of ordinary skill in the art would have predicted that replacing the electrode of Moaddeb with a structure similar to that described in Skalsky would result in a structure that attaches to tissue through tissue ingrowth. As such, those of ordinary skill in the art looking for ideas to improve the Moaddeb catheter would not have predicted any beneficial result from the modification suggested by the Examiner. Indeed, those of ordinary skill would predict that the resulting device would attach to tissue through tissue ingrowth, significantly altering the function of the Moaddeb device, and rendering the Moaddeb catheter non-operational.

Furthermore, although the Examiner asserts that "[t]he skilled artisan...would realize that any porous electrode may be fabricated in [the Skalsky] manner and continue to be used for its intended purpose," the Examiner appears to also argue that those of ordinary skill in the art would have used the Skalsky configuration for a purpose *other than* its intended purpose. In particular, the intended purpose of the Skalsky device is to promote tissue ingrowth in order to affix a pacing lead to tissue. However, the Examiner argues that those of ordinary skill in the art would have used the Skalsky device in the Moaddeb device for a *different purpose*, i.e., as an electrode on a catheter used for temporary and relatively short procedures. As the Moaddeb catheter is intended for temporary and relatively short procedures, an electrode that *affixes* to tissue would render the Moaddeb catheter non-operational.

Notably, the Examiner does not argue that a device that affixes to tissue would not significantly alter the function of the Moaddeb device. Instead, the Examiner argues that those of ordinary skill in the art would not have been required to use the Skalsky device within the Moaddeb device "in the exact same manner." Office action, page 4. However, as noted in MPEP §2143.02, to establish obviousness through a reasonable expectation of success, the Examiner must show that "one skilled in the art could have combined the elements as claimed by known methods *with no change in their respective functions*." Here, using the Skalsky device in the Moaddeb catheter would necessarily result in a material change in the function of the Skalsky device. Specifically, as the Skalsky device functions to affix a lead to tissue, its incorporation into the Moaddeb device, which functions to perform temporary and short procedures would require changing the Skalsky device such that it does *not* attach to tissue. As such, the Skalsky device would no longer perform its intended function. Conversely, if the function of the Skalsky device remains unchanged, the function of the Moaddeb catheter would be materially altered since the Skalsky device functions to attach to tissue which would prevent the Moaddeb device from being used for temporary procedures. Accordingly, those of ordinary skill in the art could *not* have combined the Skalsky lead with the Moaddeb catheter *with no change in their respective functions*. Therefore, those of ordinary skill in the art would not have combined Moaddeb and Skalsky in the manner suggested by the Examiner.

In addition, Skalsky fails to disclose a thin metal coating adapted to *cover* the non-conductive porous material, as recited in independent claims 1 and 15, a conductive porous coating generally *encapsulating* the non-conductive porous material, as recited in independent claim 29, or an *inner* non-conductive porous material and an *outer* conductive porous material, as recited in independent claim 30. Rather, Skalsky discloses electrode leaves (66) *disposed in grooves* (64) in the porous substrate (60) such that the leaves (66) are *substantially flush with the porous substrate* (60). See column 5, lines 43-47. As the leaves (66) and the porous substrate (60) are *flush*, the leaves are not adapted to *cover* the porous substrate, as recited in independent claims 1 and 15, do not generally *encapsulate* the porous substrate, as recited in independent claim 29, and do not form an *inner* non-conductive porous material and an *outer* conductive porous material, as recited in independent claim 30.

With respect to Truckai, the Examiner relies on this reference as disclosing a thickness for the conductive porous coating or thin metal coating recited in the present claims. In particular, the Examiner argues that providing a coating having the recited thickness would have been an "obvious design consideration since [Truckai] fairly teach that conductive coatings of that thickness are generally known in the art." January 10, 2010 Office action, page 4. However, Truckai is directed to polymer embolic elements for the occlusion of vascular formations, and the Truckai device is designed to controllably promote and create a coagulum of a certain thickness *about the element*. Abstract; column 3, lines 19-22 and 63-65. In significant contrast, Skalsky appears to disclose much thicker electrode leaves and the Skalsky lead is designed to facilitate attachment of the lead to tissue by promoting tissue ingrowth. See column 2, line 54 to column 3, line 8. In particular, Skalsky discloses electrode leaves made of biocompatible conductive material with a thickness of 50 to 300 microns, which is 150 to 250 times greater than that recited in the present claims. Given that Skalsky expressly describes dramatically thicker electrode leaves, and that the Skalsky pacing lead is designed to perform a significantly different function, those of ordinary skill in the art would not have predicted that dramatically reducing the thickness of the Skalsky electrode leaves would also promote tissue ingrowth and allow the Skalsky lead to function in the same manner. Accordingly, those of ordinary skill in the art would not have been motivated to reduce the thickness of the Skalsky electrode leaves as suggested by the Examiner. Moreover, Truckai does not appear to teach or suggest a *porous* conductive coating, and as such, does not appear to teach or suggest any thickness of such a *porous* conductive coating. Accordingly, claims 1-30 are allowable over Moaddeb, Skalsky and Truckai.

II. Conclusion

In view of the above, Applicant submits that all of pending claims 1-30 are allowable over Moaddeb, Skalsky and Truckai. Applicant therefore respectfully requests reversal of the rejection of the pending claims.

8. CLAIM APPENDIX

1. An irrigated electrode catheter for ablating tissue, the catheter comprising:

a catheter body having proximal and distal ends and a lumen extending therethrough;

a tip section having proximal and distal ends, the proximal end of the tip section being fixedly attached to the distal end of the catheter body;

a porous tip electrode fixedly attached to the distal end of the tip section, the tip electrode comprising a non-conductive porous material and a conductive porous coating adapted to cover the non-conductive porous material, wherein the conductive porous coating has a thickness of about 0.2μm to about 2μm; and

an irrigation tube extending through the catheter body and into the porous tip electrode of the tip section, whereby fluid passing through the irrigation tube can pass through the non-conductive porous material and the conductive porous coating to reach surrounding tissue.

2. An irrigated electrode catheter according to claim 1, further comprising an electrode lead wire in electrical communication with the conductive porous coating.

3. An irrigated electrode catheter according to claim 1, wherein the non-conductive porous material is made from material selected from the group consisting of polyethylene, Teflon and ceramic.

4. An irrigated electrode catheter according to claim 1, wherein the non-conductive porous material comprises polyethylene.

5. An irrigated electrode catheter according to claim 1, wherein the conductive porous coating is made from material selected from the group consisting of platinum and gold.

6. An irrigated electrode catheter according to claim 1, wherein the conductive porous coating comprises an alloy of platinum and iridium.

7. An irrigated electrode catheter according to claim 6, wherein the alloy of platinum and iridium comprises 90% platinum and 10% iridium.

8. An irrigated electrode catheter according to claim 1, wherein fluid passes through channels between particles of the non-conductive porous material.

9. An irrigated electrode catheter according to claim 1, wherein fluid passes through channels of a webbing of the conductive porous coating.

10. An irrigated electrode catheter according to claim 1, further comprising a temperature sensing means mounted within the tip electrode.

11. An irrigated electrode catheter according to claim 1, further comprising an electromagnetic sensor mounted in the tip section.

12. An irrigated electrode catheter according to claim 1, wherein the non-conductive porous material comprises sintered polymer particles.

13. An irrigated electrode catheter according to claim 1, wherein the non-conductive porous material comprises sintered ceramic particles.

14. An irrigated electrode catheter according to claim 12, wherein the polymer particles comprises particles of polyethylene or Teflon.

15. An irrigated electrode catheter for ablating tissue, the catheter comprising:

a catheter body having an outer wall, proximal and distal ends, and a lumen extending therethrough;

a tip section comprising a segment of flexible tubing having proximal and distal ends and at least one lumen therethrough, the proximal end of the tip section being fixedly attached to the distal end of the catheter body;

a porous tip electrode fixedly attached to the distal end of the tubing of the tip section, the tip electrode having an outer surface and comprising a non-conductive porous material through which fluid can pass and a thin metal coating adapted to cover the non-

conductive porous material, wherein the thin metal coating has a thickness of about 0.2μm to about 2μm; and

an irrigation tube having proximal and distal ends extending through the central lumen in the catheter body, wherein the distal end of the irrigation tube is in fluid communication with the proximal end of the passage in the tip electrode, whereby fluid can pass through the irrigation tube, into the passage in the tip electrode and through the porous material of the tip electrode to the outer surface of the tip electrode.

16. An irrigated electrode catheter according to claim 15, further comprising an electrode lead wire in electrical communication with the thin metal coating.

17. An irrigated electrode catheter according to claim 15, wherein the non-conductive porous material is made from material selected from the group consisting of polyethylene, Teflon and ceramic.

18. An irrigated electrode catheter according to claim 15, wherein the non-conductive porous material comprises polyethylene.

19. An irrigated electrode catheter according to claim 15, wherein the thin metal coating is made from material selected from the group consisting of platinum and gold.

20. An irrigated electrode catheter according to claim 15, wherein the thin metal coating comprises an alloy of platinum and iridium.

21. An irrigated electrode catheter according to claim 20, wherein the alloy of platinum and iridium comprises 90% platinum and 10% iridium.

22. An irrigated electrode catheter according to claim 15, wherein fluid passes through channels between particles of the non-conductive porous material.

23. An irrigated electrode catheter according to claim 15, wherein fluid passes through channels of a webbing of the thin metal coating.

24. An irrigated electrode catheter according to claim 15, further comprising a temperature sensing means mounted within the tip electrode.

25. An irrigated electrode catheter according to claim 15, further comprising an electromagnetic sensor mounted in the tip section.

26. An irrigated electrode catheter according to claim 15, wherein the non-conductive porous material comprises sintered polymer particles.

27. An irrigated electrode catheter according to claim 15, wherein the non-conductive porous material comprises sintered ceramic particles.

28. An irrigated electrode catheter according to claim 26, wherein the polymer particles comprises particles of polyethylene or Teflon.

29. An irrigated electrode catheter for ablating tissue, the catheter comprising:

a catheter body;

a tip section attached to the catheter body;

a porous tip electrode fixedly attached to the tip section, the tip electrode comprising a non-conductive porous material and a conductive porous coating generally encapsulating the non-conductive porous material, wherein the conductive porous coating has a thickness of about 0.2μm to about 2μm; and

an irrigation tube extending through the catheter body and into the porous tip electrode of the tip section, whereby fluid passing through the irrigation tube can pass through the non-conductive porous material and the conductive porous coating to reach surrounding tissue.

30. An irrigated electrode catheter for ablating tissue, the catheter comprising:

a catheter body;

a tip section attached to the catheter body;

a porous tip electrode fixedly attached to the tip section, the tip electrode comprising an inner non-conductive porous material and an outer conductive porous material, wherein the outer conductive porous material has a thickness of about 0.2μm to about 2μm; and

an irrigation tube extending through the catheter body and into the porous tip electrode of the tip section, whereby fluid passing through the irrigation tube can pass through the non-conductive porous material and the conductive porous material to reach surrounding tissue.

9. EVIDENCE APPENDIX

None.

10. RELATED PROCEEDING APPENDIX

None.

Respectfully submitted,

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